

REMARKS/ARGUMENTS

Claims 23-26 and 28-32 are active in this application, claims 1-10, 12-13 and 27 having been canceled, with new claims 31-33 being added and claims 11 and 14-22 and new claim 33 being withdrawn by the Examiner due to Restriction. Claim 23 has been amended to incorporate the presence of at least one antioxidant, from claim 27, and to correct minor formalities. Claim 11 has been amended to depend from composition claim 23. Various claims have been amended to correct their dependencies. New claims 31-33 are supported by the specification and examples and original claim 9. No new matter has been added by these amendments.

Applicants note that upon indication of allowability of the elected product claims, the Examiner is requested to rejoin the non-elected method claims, as these method claims depend from product claim 23 directly or indirectly, and therefore include all limitations thereof.

The present invention relates to a pharmaceutical composition comprising (i) at least one substance of the porphyrin synthesis, esters, acids, or pharmacologically compatible salts thereof; (ii) at least one salicylate; and (iii) at least one antioxidant. The pharmaceutical composition is noted to be for the phototherapy of at least one condition selected from psoriasis and inflammatory processes of the skin and/or joints of mammals and humans, such as, in preferred embodiments, arthritis, plaque psoriasis, arthritic psoriasis and neuropathy. Applicants have found that the use of the specific combination of these three substances provides significant improvements over prior treatment methods, particularly in the treatment of diseases such as arthritis.

Claims 23-30 stand rejected under 35 U.S.C. 103 over Voet in view of Bar-Shalom. Claims 23-30 also stand rejected under 35 U.S.C. 103 over Horrobin et al in view of McMillan. None of these references, alone or in combination, render the present invention

combination obvious. Voet discloses a composition for photodynamic therapy that contains a compound such as 5-aminolevulinic acid (see paragraph [0081]) in a topical formulation that can include an antioxidant, such as ascorbic acid (see paragraph [0101]). However, as noted by the Examiner, there is no mention in Voet of the inclusion of a salicylate in the composition. The Examiner attempts to use Bar-shalom to teach a composition for treatment of dermatologic disorders comprising acetyl salicylic acid. The Examiner then takes the position that it would be obvious for one of ordinary skill to incorporate the acetyl salicylic acid of Bar-shalom into the topical composition of Voet to arrive at the present invention.

In similar fashion, the Examiner notes that Horrobin discloses a topical composition containing, among other things, acetyl salicylic acid (or its lithium salt) and an antioxidant such as ascorbic acid. The Examiner notes that Horrobin does not disclose a compound of the porphyrin synthesis such as 5-aminolevulinic acid. The Examiner then uses McMillan to attempt to overcome these deficiencies. McMillan discloses a composition containing a compound, which can include 5-aminolevulinic acid, that is used in a phototreatment to cause photothermolysis, literally the lysis of blood vessels by local overheating.

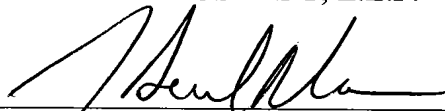
There is nothing within any of these references that would suggest the use of a salicylic acid compound in a composition for phototherapy, nor that one would want to combine the three required ingredients of the present invention into a single composition for administration to treat one of the stated diseases, particularly by way of phototherapy. Additionally, for the preferred embodiment of treatment of arthritis, none of the references appear to address any arthritis treatment at all! All of the references relate only to dermal treatments, which says nothing regarding treatment of arthritis since arthritis is NOT a dermal condition. Further, all of the references relate to topical only compositions. There is nothing in any of the references to suggest a composition that can be administered to a subject such that it is delivered internally. The present invention composition can be administered in a

variety of ways, including systemically or locally, parenterally or enterally, preferably orally or topically. In treatment of arthritis, it would be necessary for the subject to have a systemic administration, such as orally or injected, in order for the composition to get to the site of the problem. None of the references would suggest such a composition, or such a method of treatment. Based on the three references cited by the Examiner, one of ordinary skill would have no expectation that it would be possible, acceptable, or effective to combine the three required ingredients to provide a composition that can be administered systemically in order to treat diseases that are not dermatological diseases, such as arthritis. Accordingly, even if one of ordinary skill were to combine the cited references, there would be no expectation of success, particularly in treating systemic problems. Applicants have shown that the present invention can provide such treatment, and as such, the rejections should be withdrawn.

Applicants submit that the application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

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